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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,403	06/25/2003	Ben-Zion Dolitzky	2664/57104	5646
26646	7590	03/03/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			KUMAR, SHAILENDRA	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,403

Applicant(s)

DOLITZKY ET AL.

Examiner

SHAIENDRA -. KUMAR

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicants' communication filed on 12/14/04.

Claims 1-11 and 13-37 are pending in this application. Claim 12 has been canceled.

Rejection of claims 1 and 3 under 35 USC 102(e) over Ekwuribe is hereby withdrawn subsequent to applicants' amendment.

Claim Rejections - 35 USC § 103

1. Claims 1-11 and 13-32 are again rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of US'692, Tucker et al and Keil et al(US'652), all for the reasons of record and further in view of Gold(US 3,875,229).

Instant claims are directed to a process of purification and isolation of bicalutamide, wherein bicalutamide is combined with one of the solvents listed in claim 1 or may be combination of solvents as claimed in claim 6, or by seeding as claimed in claim 2.

Applicants' arguments were fully considered and were not found convincing. Applicants argue that US'692 differs from the instant method in that it does not teach various solvents as claimed herein. Tucker discloses toluene and petroleum ether as solvents, which are no m ore claimed herein. Keil discloses seeding process for the crystallization but is structurally different than claimed herein. Further more, applicants allege that none of the references teach two or more solvents for crystallization.

At the outset, applicants are claiming a simple crystallization process, which is well known in the organic chemistry. US'692, although teach only two of the solvents, it does not mean that one of ordinary skill in the art would not have used other solvents

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for crystallization, because the crystallization using claimed solvent is well known in the art, and a mere fact that US'692 has not used those solvents, does not preclude one of ordinary skill in the art to not to use those solvents. Additionally, Tucker use two different solvents and then newly cited reference, Gold(US'229) is teaching the use additional solvents such as isopropyl ether, hexane, benzene, and methanol and mixture thereof, see column 9, lines 55-56, column 10, line 62, column 11-12 etc. Finally, Keil is teaching various solvents and combination thereof for crystallization of an anilide with or without seeding, see column 1, lines 40-60. Applicants' arguments that a pyrazole group is attached in the reference as against no such group in herein, is of little if any probative value inasmuch as the functional group is anilido and one of ordinary skill in the art would be motivated to use solvents of the prior art in the crystallization of any anilido compound, with the reasonable expectation of achieving a purified compound, absent evidence to the contrary.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 34-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,797,843 in view of Ekwuribe et al(US 4,636,505) or Keil et al(US' 652).

US'843 teach process of preparing bicalutamide which is same as claimed herein. The difference between the reference and herein claimed process is that the reference claims do not teach purification process.

Ekwuribe is teaching purification of bicalutamide using a solvent, or alternatively, Keil is teaching use of two solvents for purification process.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify US'843, and purify bicalutamide as taught by Ekwuribe or Keil, because the latter references expressly teach crystallization process of anilido compound. With respect to acetonitrile, the same is well known crystallization agent in the chemical art.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

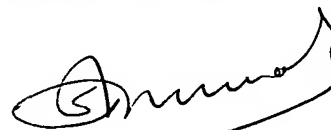
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
2/25/05